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BACTERIOLOGICAL EVALUATION OF HUMAN TISSUE FOR TRANSPLANTATION --ETC(U)
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Contract #N00014-77-C-0754

Task No. NR 204-068

9 Annual Report ~~Number One~~ no. 1,

6 Bacteriological Evaluation of Human Tissue for Transplantation and Reparative Surgery.

10 by
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Bacteriological Evaluation of Human Tissues for Transplantation and Reparative Surgery

ONR Contract N00014-77-C-0754

Submitted to

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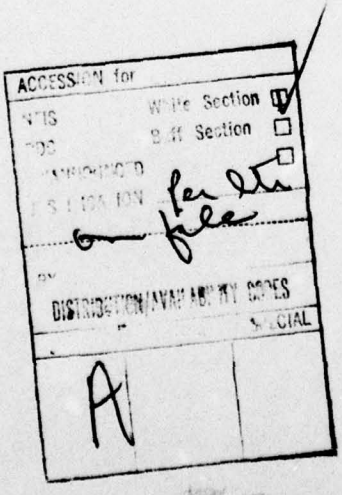

Vernon P. Perry
Director

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[redacted]0 December 1978

I. Background

This project was originally established to evaluate the enviroment in which freeze dried tissue deposits were stored and to reassess the sterility of stored tissues after various periods of time. All freeze dried tissue deposits originally procurred and stored at the Naval Medical Center were transferred to the Biomedical Research Institute and placed under a constant storage temperature of +4°C. Prior to transfer from the NNMC the tissue deposits were stored at an ambient temperature that fluctuated considerable beyond a normal room temperature of 21°C.

The reassessment of sterility for each deposit was to have begun with the initiation of the contract, however, the Human Use Committee at the NNMC decided that such a study would not be necessary and emphasis on this project was then shifted to a clinical evaluation which would expand upon the bacteriological study. To facilitate this study all data on the 5000 tissue deposits on hand were entered into the BRI computer system and programs were developed to provide for an effective inventory of the tissue. Other computer programs are being developed to provide a control of the data supplied by the civilian and military clinical collaborators for the U.S. Navy Tissue Bank, and an objective evaluation of the clinical effectiveness of the tissue processed by the U.S. Navy Tissue Bank.

II. Materials and Methods

A. Tissues

A Tissue Bank Repository and Distribution Center for the evaluation of human tissues has been established at the Biomedical Research Institute. All tissues are received from the U.S. Navy Tissue Bank in Bethesda, Maryland, and are transferred to a +4°C cold room monitored by an alarm system. All requests for tissue shipments are transmitted to the BRI by the Officer in Charge of the U.S. Navy Tissue Bank and such shipments are made as directed.

B. Inventory

A computer program was developed for entering each deposit of tissue into an inventory system. The basic information includes; a tissue deposit number; tissue type; tissue size and/or dimensions; and location in the cold room (Room number, shelving unit number, shelf number and tier). A master list of tissues is available both at the U.S. Navy Tissue Bank and at the BRI.

C. Shipments

Upon receipt of an authorization to ship each deposit of tissue, the deposit is selected from the inventory list where its specific location is identified and the tissue is packaged in plastic air bubble material and then into a cardboard box and prepared for mailing using conventional mail delivery service. Along with each shipments there is a appropriate set of instructions to be used for reconstituting the freeze dried tissue (See appendix A) and a Patient Consent Form (See appendix B).

III. Results

To date, 615 tissue shipments were made. A breakdown by tissue types is as follows:

Bone	398;	Dental Bone	97;
Skin	98;	and Fascia	22.

As previously indicated, tissues were shipped to both civilian and military collaborators. Each collaborator, prior to receiving the tissues, agrees to provide information essential to the clinical evaluation of that tissue. At periodic intervals the collaborator returns to the Tissue Bank the information requested; such information includes; pre- and post-operative x-rays when appropriate, the results of bacteriological studies conducted at the time of use, and in addition to other specific information requested based on the type of tissue used, observations on wound healing.

IV. Projected Studies

During the second year of this study, computer programs will be expanded and developed for conducting the clinical evaluation. Emphasis will be placed on providing the following information for each Tissue Bank Case:

Tissue Bank Case Number

Preoperative x-ray

Patient Authorization Form

Privacy Act

Deposit/Withdrawal Form

Operative Data

Surgical Procedure Performed

Grafting Material

Chemotherapy

Radiation Therapy

Operative Report

Pathology Report

Narrative or Discharge Summary

X-rays 6 mo, 1 year, over 1 year

Office notes 6 mo, 1 year, over 1 year

Complications

In general, the above information will be be programmed such that, for example, where forms are required a "date required" will be fed into the computer and when the collaborator supplies the required information the "data required" will be converted to a "yes" indicating that the form has been received.

A second program will be developed based on the indentity of the clinical collaborator and will evaluate the effectiveness of the collaborator in supplying the information required for an effective clinical evaluation of freeze dried tissues. Each collaborator will be identified by full name and address and a listing of all tissues shipped by deposit number. In order to continue to receive tissues as requested, the computer print out must show that the required post operative information on patients receiving prior shipped tissues have been transmitted to the Tissue Bank.

V. Other Supplemental Information

During the course of the project it was proposed that mouse burn infection model could simulate burn wound sepsis in humans and it was further proposed to study physiologically related response to endotoxin and the effect of passive immunization with highly specific rabbit antitoxin serum. Specifically, our objective was to obtain homogeneous biologically active P. aeroginosa endotoxin A in amounts necessary to produce antisera and Toxid and to provide this material to the Naval Medical Research Institute.

Endotoxin A was purified in milligram amounts from crude Pseudomonas culture filtrates using affinity chromatography. The purity, toxicity and enzymatic activity was assessed and the material supplied to the investigation at the Microbiology Department at NMRI. The toxin and antitoxin were used in passive hemagglutination and enzyme linked immunosorbent studies conducted by these investigators.

RECONSTITUTION OF FREEZE-DRIED TISSUES

1. Since RECONSTITUTED freeze-dried tissue must be UTILIZED or DISCARDED, we ask that you reconstitute only the deposits that you expect to use. Return ALL un-opened, non-reconstituted deposits as soon as possible.
2. Soft tissues should be reconstituted 30 minutes prior to use. Ground cortical and ground cancellous bone may be rehydrated for 30 minutes prior to implantation. Once reconstituted, all tissue should be kept in a refrigerator at + 4° C until used, then discarded if not used within 24 hours after hydration.
3. Bone which is to be sawed, shaped, or drilled should be reconstituted at least 3 hours prior to use. Large bone deposits such as whole femurs and long shafts should be soaked in saline solution for 18 to 24 hours in order to achieve complete hydration. Cortical plates in Baxter bottles should be laid on their side during rehydration. The same antibiotic used in pre-, intra- or post-operative surgery could be added to the saline solution.

EQUIPMENT (STERILE)

1000 or 250 ml bottle of IV saline
IV administration set
18 gauge needles
Liquid sterilizing agent
1 large Kocher clamp
1 towel clip (large)

PROCEDURE:

1. Remove metal cap from deposit jar. (If silicone or hard-rubber seal is present, cut carefully with a scalpel and remove.)
2. Wipe or soak the rubber stopper with the sterilizing solution (70% alcohol or betadine).
3. Introduce normal physiologic saline, with your choice of antibiotic, in sufficient quantity to cover the tissue completely when the container is on its side. This is best accomplished by utilizing the regular intravenous administration set.
4. Gentle intermittent agitation of the tissue is recommended, especially when the tissue being reconstituted is bone. When reconstitution is complete, the tissue should be stored in a refrigerator at + 4° C until needed at the operating table.
5. The remaining vacuum should be released by wiping the rubber stopper with a cold sterilant and inserting an 18 gauge needle prior to attempting to remove the stopper. The same procedure is used for large rubber stoppered tubes. Extreme care should be taken to avoid accidental contamination of the tissue.
6. The Kocher Clamp is used to tear the metal wrapper free around the mouth of the jar, then grasp the rubber stopper and remove with a towel clip.
7. Once the stopper is removed we recommend that a bacterial culture be taken (if an antibiotic has not been used), then care must be taken not to contaminate the lip of the unit while dispensing the allograft tissue into a sterile container.

PRECAUTIONS:

1. All tissues processed and freeze-dried prior to 1973 were soaked in a penicillin-streptomycin solution. Determinations of the residual amounts remaining in the tissue have not been done. ***Please re-check the allergic status*** of your patient before implanting this tissue.
2. Should difficulties be encountered or questions arise about tissue reconstitution, please call for assistance at 202—295-1121, U. S. Navy Tissue Bank, Naval Medical Research Institute, Bethesda, Maryland.

Exhibit A

TB0005/77

PATIENT CONSENT FORM

Patient's Name: _____

1. I understand that human tissue obtained from the U.S. Navy Tissue Bank, Bethesda, Maryland, will be transplanted into my body as part of the operative procedure I am to undergo. I have been informed that precautions have been taken to keep the tissue free of contamination, but sterility cannot be guaranteed.

2. I understand that the transplantation of this tissue is an experimental procedure, and I am willing to enter into a research agreement with my physician and the U.S. Navy Tissue Bank in order to use it. This agreement provides that in submitting to its implantation in my body, I am aware that the results of the use of this tissue cannot be guaranteed.

Witness: _____

Date: _____

Signed: _____
Patient, Parent or Guardian

Date: _____

Typed Name: _____

Address: _____

SSN# _____
(if applicable)

Please sign and return one copy to the Tissue Bank.

Exhibit B

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